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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/539,769	12/01/2005	Sylvie Sauvaigo	1169-037	6482

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EXAMINER	
JOIKE, MICHELE K	

ART UNIT	PAPER NUMBER
1636	

MAIL DATE	DELIVERY MODE
12/14/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/539,769	SAUVAIGO, SYLVIE	
	Examiner	Art Unit	
	Michele K. Joike, Ph.D.	1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 December 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *22-46* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *22-46* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *20 June 2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *6/20/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 22-46 are pending and examined.

Specification

The Abstract is objected to for containing legal phraseology.

Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 22-46 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 22 recites a method for quantitative assessment of overall and specific DNA repair. It is unclear what the metes and bunds are for this method. Is "overall" a general term? If so, then adding "specific" makes the language of the preamble contradictory. If "overall" includes "specific", then the preamble is confusing.

Claim 22 recites the limitation "the label" in line 24. There is insufficient antecedent basis for this limitation in the claim. In step (d), a labeled nucleotide triphosphate is optional. However, in step (f) it is no longer optional.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 45 and 46 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 44 recites a range from “about 1 to 5 hours”, and claim 46 recites “about 3 hours". There is no support in the specification for the term “about”. There is only support for a range of 1 to 5 hours of incubating time, or an incubation time of 3 hours. This is a new matter rejection.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 22-24, 26, 27, 32, 34, 38, 39 and 41-44 are rejected under 35 U.S.C. 102(e) as being anticipated by US 7,033,757.

Applicants claim a method for quantitative assessment of overall and specific DNA repair capacities by a) preparing a range of plasmids, each comprising distinct DNA lesions, by independent treatment of said plasmids with at least one physical or chemical treatment means or both and recovering a supercoiled fraction of each of said plasmids, b) characterizing the lesions present on each of the plasmids of said range of plasmids, c) depositing the plasmids of said range of plasmids, and at least one supercoiled control plasmid without lesions, onto a single solid support, according to a pre-established configuration A, so as to form a functionalized support divided into different zones Al to Ax, x corresponding to an integer equal to the number of biological media to-be simultaneously tested, each zone A1 to Ax comprising said range of plasmids, d) incubating said functionalized support obtained in step (c) with various repair solutions e) washing said functionalized support at least once, f) directly or indirectly measuring the signal produced by the label incorporated into the DNA during

the repair reaction in step (d), in each of said different and pre-established zones Al to Ax, g) recording and quantifying the signal corresponding to each deposit of plasmid in each zone Al to Ax, and h) determining the ratio of the signals of the plasmids comprising the lesions relative to the control plasmid jointly deposited.

US 7,033,757 (see entire patent, especially examples) teach a method for detecting whether DNA modifications have been repaired by DNA repair enzymes, specifically repair glycosylase enzymes. The DNA containing lesion can be in a plasmid and multiples are placed on an array. The lesion can be chemically created. The array is used to test multiple lesions, and the nature of an array is a solid support with divided zones for assessing different solutions. Most DNA is negatively supercoiled (as evidenced by You et al, Biophys. J.: Biophys Letters L43-L45, 2005), therefore, absent evidence to the contrary, the plasmids used are supercoiled. There is also control (wild type) DNA. When the sample has been immobilized on the support, it is washed, and treated with DNA repair enzymes. The DNA can be labeled and scanned to detect if modifications are still present, and compared to the control. The DNA can also be digested, and the fragments can be analyzed. The DNA can be double-stranded. The support can be treated to increase its affinity for the DNA. For example, the support can be coated with streptavidin to increase affinity for biotinylated DNA. This reference also reads on the methods to establish a repair profile, diagnose a repair-related disease, to assess the influence of a physical or chemical treatment means on repair capacities and for screening substances capable of modulating a repair system (claims 41-44) since these methods all comprise the exact same steps.

Allowable Subject Matter

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michele K. Joike, Ph.D. whose telephone number is 571-272-5915. The examiner can normally be reached on M-F, 9:00-6:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach can be reached on 571-272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Michele K Joike, Ph.D.
Examiner
Art Unit 1636

NANCY VOGEL
PRIMARY EXAMINER